DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 3, 2014

Orthocon Incorporated
Mr. Howard Schrayer
1 Bridge Street, Suite 121
Irvington, New York 10533

Re: K141502
Trade/Device Name: HBP4™ Hardening, Resorbable Hemostatic Bone Putty
Regulatory Class: Unclassified
Product Code: MJT
Dated: July 7, 2014
Received: July 8, 2014

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2014.10.03 15:55:00 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141502

Device Name
HBP4™ Hardening, Resorbable Hemostatic Bone Putty

Indications for Use *(Describe)*
HBP4 Hardening, Resorbable Hemostatic Bone Putty is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Contact: Howard Schrayer
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hs.ss@verizon.net

Date Prepared: September 24, 2014

Device Trade Name: HBP4™ Hardening, Resorbable Hemostatic Bone Putty

Manufacturer: Orthocon, Inc.
1 Bridge Street, Suite 121
Irvington, NY 10533

Common Name: Calcium phosphate bone hemostasis material

Classification: Unclassified

Product Code: MTJ

Primary Predicate: Skeletal Kinetics CAAP (Calcium Apatite) Bone Wax
510(k) K111538

Additional predicates: US Surgical Auto Suture Bone Wax
510(k) K971680

CP Medical Bone Wax
510(k) K024372

Ceremed Ostene® CT Bone Hemostasis Implant
510(k) K102071

Orthocon Hemostatic Bone Putty 3
510(k) K123243

Indications for Use:

HBP4 Hardening, Resorbable Hemostatic Bone Putty is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.

Device Description:

HBP4 Hardening, Resorbable Hemostatic Bone Putty is a sterile, biocompatible, resorbable material of putty-like consistency for use in the control of bleeding from bone surfaces. The single use HBP4 *device* contains two separate components of putty-like consistency comprised of granular calcium phosphate, calcium stearate, vitamin E acetate, a triglyceride, a polyalcohol and a mixture of a lactide-diester and polyester-based polymers. When mixed together, the components of the HBP4 device form a resorbable putty-like material that can be applied directly to bleeding bone. The resulting hardening material is primarily comprised of calcium phosphate. HBP4 must be mixed immediately prior to use.

When applied to surgically cut or traumatically damaged bone, HBP4 Hardening, Resorbable Hemostatic Bone Putty achieves local control of bleeding by acting as a mechanical barrier (tamponade).

Substantial Equivalence and Predicate Devices:

The device was shown to be substantially equivalent to previously cleared bone wax devices including Skeletal Kinetics CAAP (Calcium Apatite) Bone Wax (K111538), US Surgical Auto Suture Bone Wax (K971680), CP Medical Bone Wax (K024372), Ceremed Ostene CT Bone Hemostasis Implant (K102071) and Orthocon Hemostatic Bone Putty 3 Resorbable Hemostatic Bone Putty (K123243). Additional bone wax devices are available in a variety of forms (e.g., waxes, putties, and hardening materials) and some are permanent implants while others are resorbable.

Technological Characteristics:

The tables below provide comparisons of HBP4 Hardening, Resorbable Hemostatic Bone Putty with the predicate devices.

Predicate Comparison Table

Manufacturer	Orthocon, Inc.	Skeletal Kinetics	US Surgical
Trade Name	HBP4 Hardening, Resorbable Hemostatic Bone Putty	CAAP (Calcium Apatite) Bone Wax	Auto Suture Bone Wax
510(k) Number	Subject Device	K111538	K971680
Type of Device/ Product Code	Bone hemostat / MTJ	Bone hemostat / MTJ	Bone hemostat / MTJ
Indications for Use	HBP4 Hardening, Resorbable Hemostatic Bone Putty is indicated in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade	CAAP (Calcium Apatite) Bone Wax is indicated to control bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade	Auto Suture Bone Wax is indicated for use in the control of bleeding from bone surfaces
Intended Use	Bone hemostasis	Bone hemostasis	Bone hemostasis
Mechanism of Action	Mechanical tamponade that occludes vascular openings in damaged bone	Mechanical tamponade that occludes vascular openings in damaged bone	Mechanical tamponade that occludes vascular openings in damaged bone
Form of Device	HBP4 Hardening, Resorbable Hemostatic Bone Putty is formulated as a two-part putty/putty device that forms a “settable” (hardening) putty when manually mixed at the time of surgery.	CAAP (Calcium Apatite) Bone Wax is formulated as a two-part powder/liquid system that forms a “settable” (hardening) putty when manually mixed at the time of surgery.	Paste-like material.

Radiopacity	Radiopaque – Contains calcium phosphate	Radiopaque – Contains calcium apatite	Radiopaque – Contains β-tricalcium phosphate
Materials	Sterile mixture of two separate components of putty-like consistency comprised of calcium phosphate, calcium stearate, vitamin E acetate, triglyceride, polyalcohol and a mixture of a lactide-diester and polyester-based absorbable polymers. HBP4 is to be mixed immediately prior to use. Resulting hardening material from the two putties is primarily comprised of calcium phosphate similar to the mineral phase of native bone tissue.	A sterile kit containing calcium phosphate powder, dilute sodium silicate liquid, and a mixing system (mixing bowl, pestle and spatula). CAAP Bone wax is to be mixed immediately prior to use. Resulting hardening material from the paste is primarily comprised of calcium phosphate, similar to the mineral phase of native bone tissue.	A sterile mixture of glycolide, caprolactone, mannitol and β-tricalcium phosphate. The copolymer derived from glycolide and caprolactone is the same copolymer used to coat US Surgical's POLYSORB Suture.
Resorbable	Yes	Yes	Yes

Resorption Time	Greater than 30 days primarily due to presence of calcium phosphate.	Greater than 30 days primarily due to presence of calcium phosphate	Greater than 30 days primarily due to presence of calcium phosphate.
Method of Application	Manually applied and spread onto bone tissue	Manually applied and spread onto bone tissue	Manually applied and spread onto bone tissue
Degradation Process	The non-calcium salt and non-polymeric components degrade via dissolution; the polymer degrades via hydrolysis and calcium salts degrade via chemical dissolution and/or cellular removal	Believed to be combination of chemical dissolution and/or cellular removal	Copolymer degrades via hydrolysis; calcium phosphate degrades via combination of chemical dissolution and cellular removal
Sterility	Provided sterile for single use by gamma irradiation	Provided sterile for single use by gamma irradiation	Provided sterile for single use by gamma irradiation

Predicate Comparison Table (cont'd)

Manufacturer	CP Medical	Ceremed	Orthocon, Inc.
Trade Name	CP Medical Bone Wax	Ostene® CT Bone Hemostasis Implant	Hemostatic Bone Putty 3 Resorbable Hemostatic Bone Putty
510(k) Number	K024372	K102071	K123243
Type of Device/ Product Code	Bone hemostat / MTJ	Bone hemostat / MTJ	Bone hemostat / MTJ
Indications for Use	The CP Medical Bone Wax is indicated for use in the control of bleeding from bone surfaces**.**	Ostene® CT is indicated for use as a water-soluble implant material and for use **in** the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy	Hemostatic Bone Putty 3 is indicated for the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.
Intended Use	Bone hemostasis	Bone hemostasis	Bone hemostasis
Mechanism of Action	Mechanical tamponade that occludes vascular openings in damaged bone	Mechanical tamponade that occludes vascular openings in damaged bone	Mechanical tamponade that occludes vascular openings in damaged bone
Form of Device	A hard wax-like material that must be warmed by kneading prior to use,	An odorless, opaque wax-like material designed to be utilized directly out of the package. It can be softened and increased in stickiness by warming and by additional handling and manipulation	Putty-like material that does not require kneading prior to application.

Radiopacity	Not Radiopaque	Not Radiopaque	Radiopaque – Contains β-tricalcium phosphate
Materials	CP Medical bone wax is a sterile mixture of bees wax and paraffin.	Ostene® CT is a sterile mixture of water-soluble alkylene oxide copolymers	Hemostatic Bone Putty 3 is a mixture of alkylene oxide polymer-based materials, vitamin **E** acetate, granular calcium phosphate and carboxymethylcellulose sodium salt.
Resorbable	Non-resorbable	Yes	Yes
Resorption Time	Permanent implant	Less than 30 days	Greater than 30 days primarily due to presence of calcium phosphate.
Method of Application	Manually applied and spread onto bone tissue	Manually applied and spread onto bone tissue	Manually applied and spread onto bone tissue
Degradation Process	Does not degrade – has been found to be present years after implantation	Degrades via dissolution	The non-calcium salt degrade via dissolution; the calcium salts degrade via chemical dissolution and/or cellular removal
Sterility	Provided sterile for single use by gamma irradiation	Provided sterile for single use by irradiation	Provided sterile for single use by gamma irradiation

Performance Testing:

Bench testing, biocompatibility and animal functionality testing performed on HBP4™ Hardening, Resorbable Hemostatic Bone Putty demonstrate that the device is substantially equivalent to predicate devices in intended use, technological characteristics, and performance. This testing included the following:

Bench Testing was conducted to verify the device's handling properties, to characterize the device's performance over a range of temperatures and to evaluate the device's dissolution properties. The following bench studies were completed: relative stiffness, spreadability, stickiness, temperature sensitivity, electrocautery compatibility, dissolution and swelling.

Biocompatibility Testing was conducted to evaluate the device's biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted on the final, finished, gamma-irradiated sterile device in accordance with the GLP requirements: irritation, sensitization, acute systemic toxicity, genotoxicity, implantation, subacute systemic toxicity, chronic systemic toxicity, hemolysis, endotoxicity and pyrogenicity.

Animal Testing included animal studies to demonstrate intraoperative *in vivo* hemostasis, resistance to irrigation, and to characterize resorption time.

Conclusion

HBP4 is substantially equivalent to previously cleared bone wax devices with respect to intended use, general technological characteristics and performance.